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NOTICE OF ALLOWANCE AND FEE(S) DUE

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05/04/2010

MCANDREWS HELD & MALLOY, LTD 500 WEST MADISON STREET SUITE 3400 CHICAGO, IL 60661 EXAMINER

MEHTA, PARIKHA SOLANKI

ART UNIT PAPER NUMBER

3737

DATE MAILED: 05/04/2010

	APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
	10/616,319	07/09/2003	Heidi D. Zhang	133860-2 (MHM	1891
-	PITT E OF INIVENITION, II	TED ACCIDID DDE ACT CO	DEENING DEVICE	14882US02)	

TITLE OF INVENTION: ULTRASOUND BREAST SCREENING DEVICE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	08/04/2010

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							(Date)	
APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR		ATTO	RNEY DOCKET NO.	CONFIRMATION NO.	
10/616,319	07/09/2003	•	Heidi D. Zhang		1.	33860-2 (MHM	1891	
TITLE OF INVENTION	V: ULTRASOUND BRE.	AST SCREENING DEVI	ICE			14882US02)		
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APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSU	E FEE	TOTAL FEE(S) DUE	DATE DUE	
nonprovisional	NO	\$1510	\$300	\$0		\$1810	08/04/2010	
EXAM	IINER	ART UNIT	CLASS-SUBCLASS					
MEHTA, PARI	KHA SOLANKI	3737	600-459000					
1. Change of correspond CFR 1.363).	ence address or indication	on of "Fee Address" (37	2. For printing on the patent front page, list					
	oondence address (or Cha	ange of Correspondence	(1) the names of up to 3 registered patent attorneys 1—or agents OR, alternatively,					
☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. ☐ "Fee Address" indication (or "Fee Address" Indication form			(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to					
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Please check the appropr	riate assignee category or	r categories (will not be pr	rinted on the patent):	Individual 🖵 Co	orporati	on or other private gro	up entity 🔲 Government	
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/616,319	07/09/2003	Heidi D. Zhang	133860-2 (MHM 14882US02)	1891	
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MCANDREWS :	HELD & MALLOY,	MEHTA, PARIKHA SOLANKI			
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CHICAGO, IL 606	061		DATE MAILED: 05/04/201	0	

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 1758 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 1758 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

	Application No.	Applicant(s)	
	10/616,319	ZHANG ET AL.	
Notice of Allowability	Examiner	Art Unit	
	PARIKHA S. MEHTA	3737	
The MAILING DATE of this communication apperall claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RI	(OR REMAINS) CLOSED in to or other appropriate communing GHTS. This application is subsended in MPEP 1308.	nis application. If not included ication will be mailed in due course. 1	
1. This communication is responsive to the BPAI decision of 2	<u>2/24/10</u> .		
2. X The allowed claim(s) is/are <u>1,3-24,26-53,56,59-62 and 64-</u>	<u>70</u> .		
 3. Acknowledgment is made of a claim for foreign priority ur a) All b) Some* c) None of the: 1. Certified copies of the priority documents have 2. Certified copies of the priority documents have 	been received.	•	
3. Copies of the certified copies of the priority do	···	<u> </u>	the
International Bureau (PCT Rule 17.2(a)).		<u> </u>	
* Certified copies not received:			
Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONM THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. 4. A SUBSTITUTE OATH OR DECLARATION must be subm	IENT of this application. itted. Note the attached EXAN	IINER'S AMENDMENT or NOTICE C	
INFORMAL PATENT APPLICATION (PTO-152) which give	, , ,	eclaration is deficient.	
5. CORRECTED DRAWINGS (as "replacement sheets") mus			
(a) ☐ including changes required by the Notice of Draftspers		PTO-948) attached	
1) hereto or 2) to Paper No./Mail Date		. H Office	
 (b) ☐ including changes required by the attached Examiner's Paper No./Mail Date Identifying indicia such as the application number (see 37 CFR 1) 			
each sheet. Replacement sheet(s) should be labeled as such in the			
 DEPOSIT OF and/or INFORMATION about the depo- attached Examiner's comment regarding REQUIREMENT 			
Attachment(s)	5 □ Notice of Info	emal Datant Application	
 Notice of References Cited (PTO-892) D Notice of Draftperson's Patent Drawing Review (PTO-948) 		rmal Patent Application	
 Information Disclosure Statements (PTO/SB/08), 	Paper No./M	ail Date mendment/Comment	
Paper No./Mail Date4. ☐ Examiner's Comment Regarding Requirement for Deposit		atement of Reasons for Allowance	
of Biological Material	9. 🔲 Other		

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EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Joseph Butscher on 30 March 2010.

The application has been amended as follows:

1. (Currently amended) An ultrasound breast imaging assembly comprising:

first and second compression plates that are angled with respect to one another;

a breast compression area defined between said first and second compression plates;

at least one pivot assembly allowing relative motion between said first and second compression plates, said at least one pivot assembly being operatively connected to each of said first and second compression plates, wherein said at least one pivot assembly comprises first and second pivot assemblies, wherein said first pivot assembly is operatively connected to said first compression plate, and said second pivot assembly is operatively connected to said second compression plate; and

an ultrasound probe having an active matrix array (AMA) positioned on one of said first and second compression plates, said ultrasound probe being configured to translate over said one of said first and second compression plates.

2. (Canceled)

3. (Original) The ultrasound breast imaging assembly of claim 1, wherein one of said first and second compression plates remains in a fixed orientation with respect to the other.

4. (Original) The ultrasound breast imaging assembly of claim 1, wherein the relative motion between said first and second compression plates occurs over an arcuate path.

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- 5. (Original) The ultrasound breast imaging assembly of claim 1, wherein said at least one pivot assembly comprises a spring member that connects said first compression plate to said second compression plate.
- 6. (Currently amended) The ultrasound breast imaging assembly of claim 1, wherein said ultrasound breast imaging assembly comprises an upright member supported by a base, said first empression plate being operatively connected to a first pivot assembly, which is in turn positioned on a first portion of said upright member, and said second compression plate being operatively connected to a second pivot assembly, which is in turn positioned on a second portion of said upright member.
- 7. (Currently amended) The ultrasound breast imaging assembly of claim 1, wherein said ultrasound breast imaging assembly comprises an upright member supported by a base, said first eompression plate being operatively connected to a first pivot assembly, which is in turn connected to a first extension member, which is in turn translationally secured to said upright member.
- 8. (Original) The ultrasound breast imaging assembly of claim 7, wherein said second compression plate remains in a fixed orientation.
- 9. (Currently amended) The ultrasound breast imaging assembly of claim 7, wherein said second compression plate is operatively connected to a second pivot assembly, which is in turn connected to a second extension member, which is in turn translationally secured to said upright member.
- 10. (Original) The ultrasound breast imaging assembly of claim 7, wherein said first extension member is perpendicular to said upright member, and wherein said first extension member translates along said upright member while said first and second compression plates remain angled with respect to one another, wherein the angle between the first and second compression plates changes when a breast is compressed therebetween.
- 11. (Original) The ultrasound breast imaging assembly of claim 1, wherein said first and second compression plates are configured to compress a breast in said breast compression area so that said probe may image the breast, and wherein said first and second compression plates remain angled with respect to

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one another, wherein the angle between the first and second compression plates changes upon the relative

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motion between the first and second compression plates.

12. (Original) The ultrasound breast imaging assembly of claim 1, wherein said first and second

compression plates are radiolucent.

13. (Original) The ultrasound breast imaging assembly of claim 1, wherein said first and second

compression plates are configured to adequately contact the breast for imaging even though the breast is

not substantially flattened.

14. (Original) The ultrasound breast imaging assembly of claim 1, wherein said ultrasound

breast imaging assembly is used in conjunction with an x-ray mammography system.

15. (Original) The ultrasound breast imaging assembly of claim 14, wherein said ultrasound

breast imaging assembly is secured to a portion of said x-ray mammography system.

16. (Original) The ultrasound breast imaging assembly of claim 1, wherein said AMA

comprises a plurality of rows of a plurality of ultrasound elements.

17. (Original) The ultrasound breast imaging assembly of claim 16, wherein at least one group

of said plurality of ultrasound elements is selectively activated during an imaging procedure.

18. (Previously presented) The ultrasound breast imaging assembly of claim 1,

further comprising an upright member supported by a base, and a swivel member that connects said at

least one pivot assembly and first and second compression plates to said upright member, wherein said

swivel member is configured to rotate said first and second compression plates through a plurality of

imaging orientations.

19. (Original) The ultrasound breast imaging assembly of claim 18, wherein said plurality of

imaging orientations comprise a cranio-caudal (CC) orientation and a mediolateral oblique (MLO)

orientation.

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20. (Original) The ultrasound breast imaging assembly of claim 1, wherein said ultrasound breast imaging assembly is configured to allow a patient to be imaged in a standard mammography position.

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- 21. (Original) The ultrasound breast imaging assembly of claim 1, wherein one of said first and second compression plates comprises a sonolucent compression film, and wherein said ultrasound probe is configured to translate over said sonolucent compression film.
- 22. (Original) The ultrasound breast imaging assembly of claim 1, wherein one of said first and second compression plates comprises a sound absorbing stabilization plate.
- 23. (Original) The ultrasound breast imaging assembly of claim 1, wherein the first and second compression plates remain angled with respect to one another during the relative motion between said first and second compression plates, and wherein the angle between said first and second compression plates changes during the relative motion between the first and second compression plates.
 - 24. (Currently amended) A breast imaging and display system comprising:
 - a central processing unit (CPU);
 - an imaging workstation in electrical communication with said CPU; and
- an ultrasound breast imaging assembly operatively connected to, and in electrical communication with, said CPU, said ultrasound breast imaging assembly comprising:
 - an upper compression plate;
- a lower compression plate, wherein the planes of said upper and lower compression plates are angled with respect to one another;
 - a breast compression area defined between said upper and lower compression plates;
- at least one pivot assembly allowing relative motion between said upper and lower compression plates while said planes of said upper and lower compression plates remain angled with respect to one another, said at least one pivot assembly being operatively connected to each of said upper and lower compression plates, wherein the angle between said compression plates changes during the relative motion between said first and second compression plates, wherein said at least one pivot assembly comprises upper and lower pivot assemblies, wherein said upper pivot assembly is operatively

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connected to said upper compression plate, and said lower pivot assembly is operatively connected to said lower compression plate; and

an ultrasound probe having an active matrix array (AMA) positioned on one of said upper and lower compression plates, said ultrasound probe being configured to translate over said one of said upper and lower compression plates.

25. (Canceled)

26. (Original) The system of claim 24, wherein one of said upper and lower compression plates remains in a fixed orientation with respect to the other.

27. (Original) The system of claim 24, wherein the upper compression plate moves relative to said lower compression plate by pivoting with respect to said lower compression plate over an arcuate path.

28. (Original) The system of claim 24, wherein said at least one pivot assembly comprises a spring member that connects said upper compression plate to said lower compression plate.

29. (Currently amended) The system of claim 24, wherein said ultrasound breast imaging assembly comprises an upright member supported by a base, said upper compression plate being operatively connected to an upper pivot assembly, which is in turn positioned on an upper portion of said upright member, and said lower compression plate being operatively connected to a lower pivot assembly, which is in turn positioned on a lower portion of said upright member.

30. (Currently amended) The system of claim 24, wherein said ultrasound breast imaging assembly comprises an upright member supported by a base, <u>and</u> said upper compression plate being operatively connected to an upper pivot assembly, which is in turn connected to an upper extension plate, which is in turn translationally secured to said upright member.

31. (Previously presented) The system of claim 30, wherein said lower compression plate remains in a fixed orientation with respect to said upright member.

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- 32. (Currently amended) The system of claim 30, wherein said lower compression plate is operatively connected to a lower pivot assembly, which is in turn connected to a lower extension member, which is in turn translationally secured to said upright member.
- 33. (Original) The system of claim 30, wherein said upper extension member is perpendicular to said upright member, and wherein said upper extension member translates over said upright member.
- 34. (Original) The system of claim 24, wherein said upper and lower compression plates are configured to compress a breast in said breast compression area so that said probe may image the breast, and wherein said upper and lower compression plates remain angled with respect to one another during imaging of the breast.
- 35. (Original) The system of claim 24, wherein said upper and lower compression plates are configured to adequately contact the breast for imaging even though the breast is not substantially flattened.
- 36. (Original) The system of claim 24, wherein said ultrasound breast imaging assembly is used with an x-ray mammography system.
- 37. (Original) The system of claim 36, wherein said ultrasound breast imaging assembly is secured to a portion of said x-ray mammography system.
- 38. (Original) The system of claim 24, wherein said AMA comprises a plurality of rows of a plurality of ultrasound elements.
- 39. (Original) The system of claim 38, wherein at least one group of said plurality of ultrasound elements is selectively activated and deactivated during an imaging procedure.
- 40. (Previously presented) The system of claim 24, further comprising an upright member supported by a base, and a swivel member that connects said at least one pivot assembly and upper and

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lower compression plates to said upright member, wherein said swivel member is configured to rotate said upper and lower compression plates through a plurality of imaging orientations.

- 41. (Original) The system of claim 40, wherein said plurality of imaging orientations comprise a cranio-caudal (CC) orientation and a mediolateral oblique (MLO) orientation.
- 42. (Original) The system of claim 24, wherein said ultrasound breast imaging assembly is configured to allow a patient to be imaged in a standard mammography position.
- 43. (Original) The system of claim 24, wherein one of said upper and lower compression plates comprises a sonolucent compression film, and wherein said ultrasound probe is configured to translate over said sonolucent compression film.
- 44. (Original) The system of claim 24, wherein one of said upper and lower compression plates comprises a sound absorbing stabilization plate.
- 45. (Original) The system of claim 24, wherein said CPU receives image data from said ultrasound probe and automatically analyzes said image data for at least one of lesions, cysts and microcalcifications.
- 46. (Original) The system of claim 24, wherein said image workstation comprises a monitor, wherein said CPU displays an ultrasound image on said monitor, and wherein said image is derived from said ultrasound probe imaging a breast.
- 47. (Original) The system of claim 46, wherein said CPU also displays an x-ray mammographic image on said monitor within close proximity of said ultrasound image.
- 48. (Original) The system of claim 47, wherein said ultrasound image is registered with said x-ray mammographic image.
- 49. (Original) The system of claim 46, wherein said ultrasound image is a representation of an individual ultrasound slice.

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50. (Original) The system of claim 46, wherein said ultrasound image is a representation of a

thick slice, wherein said thick slice comprises a plurality of individual ultrasound slices.

51. (Original) The system of claim 24, wherein said image workstation comprises a monitor,

and wherein said CPU displays a CINE loop of a plurality of individual ultrasound slices on said monitor.

52. (Currently amended) An ultrasound breast imaging assembly comprising:

a first and second compression plates, said first and second compression plates being angled with

respect to one another, one of said first and second compression plates comprising a sonolucent

compression film, the other of said first and second compression plates comprising a sound absorbing

stabilization plate; and said ultrasound probe configured to translate over said sonolucent compression

film;

a breast compression area defined between said first and second compression plates, wherein said

first and second compression plates are configured to compress a breast in said breast compression area so

that said probe may image the breast, and wherein said first and second compression plates remain angled

with respect to one another during the compression;

at least one pivot assembly allowing relative motion over an arcuate path between said first and

second compression plates, said at least one pivot assembly being operatively connected to each of said

first and second compression plates, wherein said at least one pivot assembly is operatively connected to

at least one of said first and second compression plates, and wherein the angle between the first and

second compression plates changes upon the relative motion between the first and second compression

plates;

an upright member supported by a base, said first compression plate being operatively connected

to a first pivot assembly, which is in turn positioned on a first portion of said upright member, said second

compression plate being operatively connected to a second pivot assembly, which is in turn positioned on

a second portion of said upright member; and

an ultrasound probe having an active matrix array (AMA) positioned on one of said first and

second compression plates, wherein said AMA comprises a plurality of rows having a plurality of

ultrasound elements; and wherein said ultrasound probe is configured to translate over said one of said

first and second compression plates.

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53. (Original) The ultrasound breast imaging assembly of claim 52, wherein said at least one pivot assembly comprises a spring member that connects said first compression plate to said second

compression plate.

54. (Canceled)

55. (Canceled)

56. (Original) The ultrasound breast imaging assembly of claim 52, wherein said second

compression plate remains in a fixed orientation.

57. (Canceled)

58. (Canceled)

59. (Original) The ultrasound breast imaging assembly of claim 52, wherein said first and

second compression plates are configured to adequately compress the breast for imaging even though the

breast is not substantially flattened.

60. (Original) The ultrasound breast imaging assembly of claim 52, wherein said ultrasound

breast imaging assembly is used in conjunction with an x-ray mammography system.

61. (Original) The ultrasound breast imaging assembly of claim 60, wherein said ultrasound

breast imaging assembly is secured to a portion of said x-ray mammography system.

62. (Original) The ultrasound breast imaging assembly of claim 52, wherein at least one group

of said plurality of ultrasound elements is selectively activated and deactivated during an imaging

procedure.

63. (Canceled)

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64. (Original) The ultrasound breast imaging assembly of claim 63, wherein said plurality of imaging orientations comprise a cranio-caudal (CC) orientation and a mediolateral oblique (MLO) orientation.

65. (Original) The ultrasound breast imaging assembly of claim 52, wherein said ultrasound breast imaging assembly is configured to allow a patient to be imaged in a standard mammography position.

66. (New) An ultrasound breast imaging assembly comprising:

first and second compression plates that are angled with respect to one another;

a breast compression area defined between said first and second compression plates;

at least one pivot assembly allowing relative motion between said first and second compression plates, said at least one pivot assembly being operatively connected to each of said first and second compression plates;

an upright member supported by a base, said first compression plate being operatively connected to a first pivot assembly, which is in turn positioned on a first portion of said upright member, said second compression plate being operatively connected to a second pivot assembly, which is in turn positioned on a second portion of said upright member; and

an ultrasound probe having an active matrix array (AMA) positioned on one of said first and second compression plates, said ultrasound probe being configured to translate over said one of said first and second compression plates.

67. (New) An ultrasound breast imaging assembly comprising:

first and second compression plates that are angled with respect to one another;

a breast compression area defined between said first and second compression plates;

at least one pivot assembly allowing relative motion between said first and second compression plates, said at least one pivot assembly being operatively connected to each of said first and second compression plates;

an upright member supported by a base;

a swivel member that connects said at least one pivot assembly and first and second compression plates to said upright member, wherein said swivel member is configured to rotate said first and second compression plates through a plurality of imaging orientations; and

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an ultrasound probe having an active matrix array (AMA) positioned on one of said first and second compression plates, said ultrasound probe being configured to translate over said one of said first and second compression plates.

68. (New) A breast imaging and display system comprising:

a central processing unit (CPU);

an imaging workstation in electrical communication with said CPU;

an ultrasound breast imaging assembly operatively connected to, and in electrical communication with, said CPU, said ultrasound breast imaging assembly comprising:

an upper compression plate;

a lower compression plate, wherein the planes of said upper and lower compression plates are angled with respect to one another;

a breast compression area defined between said upper and lower compression plates;

at least one pivot assembly allowing relative motion between said upper and lower compression plates while said planes of said upper and lower compression plates remain angled with respect to one another, said at least one pivot assembly being operatively connected to each of said upper and lower compression plates, wherein the angle between said compression plates changes during the relative motion between said first and second compression plates;

an upright member supported by a base, said upper compression plate being operatively connected to an upper pivot assembly, which is in turn positioned on an upper portion of said upright member, said lower compression plate being operatively connected to a lower pivot assembly, which is in turn positioned on a lower portion of said upright member; and

an ultrasound probe having an active matrix array (AMA) positioned on one of said upper and lower compression plates, said ultrasound probe being configured to translate over said one of said upper and lower compression plates.

69. (New) A breast imaging and display system comprising:

a central processing unit (CPU);

an imaging workstation in electrical communication with said CPU;

an ultrasound breast imaging assembly operatively connected to, and in electrical communication with, said CPU, said ultrasound breast imaging assembly comprising:

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an upper compression plate;

a lower compression plate, wherein the planes of said upper and lower compression plates are angled with respect to one another;

a breast compression area defined between said upper and lower compression plates;

at least one pivot assembly allowing relative motion between said upper and lower compression plates while said planes of said upper and lower compression plates remain angled with respect to one another, said at least one pivot assembly being operatively connected to each of said upper and lower compression plates, wherein the angle between said compression plates changes during the relative motion between said first and second compression plates;

an upright member supported by a base;

a swivel member that connects said at least one pivot assembly and upper and lower compression plates to said upright member, wherein said swivel member is configured to rotate said upper and lower compression plates through a plurality of imaging orientations; and

an ultrasound probe having an active matrix array (AMA) positioned on one of said upper and lower compression plates, said ultrasound probe being configured to translate over said one of said upper and lower compression plates.

70. (New) An ultrasound breast imaging assembly comprising:

a first compression plate and a second compression plate, said first and second compression plates being angled with respect to one another, one of said first and second compression plates comprising a sonolucent compression film, the other of said first and second compression plates comprising a sound absorbing stabilization plate;

a breast compression area defined between said first and second compression plates, wherein said first and second compression plates are configured to compress a breast in said breast compression area so that said probe may image the breast, and wherein said first and second compression plates remain angled with respect to one another during the compression;

at least one pivot assembly allowing relative motion over an arcuate path between said first and second compression plates, said at least one pivot assembly being operatively connected to each of said first and second compression plates, and wherein the angle between the first and second compression plates changes upon the relative motion between the first and second compression plates;

an upright member supported by a base;

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a swivel member that connects said at least one pivot assembly and first and second compression plates to said upright member, wherein said swivel member is configured to rotate said first and second

compression plates through a plurality of imaging orientations; and

an ultrasound probe having an active matrix array (AMA) positioned on one of said first and second compression plates, wherein said AMA comprises a plurality of rows having a plurality of ultrasound elements; and wherein said ultrasound probe is configured to translate over said one of said

first and second compression plates.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PARIKHA S. MEHTA whose telephone number is (571)272-3248. The examiner can normally be reached on M-F, 8 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571.272.4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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